

DEPARTMENT OF THE ARMY
HEADQUARTERS, WALTER REED ARMY MEDICAL CENTER
6900 Georgia Avenue, NW
Washington, D.C. 20307-5001

WRAMC Regulation
No. 40-68

1 July 2002

Medical Services
PERFORMANCE IMPROVEMENT/PATIENT SAFETY/RISK MANAGEMENT PLAN

1. Purpose. The purpose of this regulation is to establish a hospital-wide Performance Improvement, Patient Safety and Risk Management Plan. Functions of this plan provide a background of Performance Improvement philosophy and set responsibilities and procedures in implementing this plan. The scope of this plan extends to each hospital element and to each individual employee. The objectives are to design processes, monitor performance through data collection, analyze current performance, and improve and sustain improved performance with the final goal being to improve patient outcomes.

2. References.

- a. AR 15-6, Procedures for Investigating Officers and Boards of Officers, 11 MAY 88
- b. AR 40-48, Non-physician Health Care Providers, 7 NOV 00
- c. AR 40-66, Medical Records and Quality Assurance Administration, 3 MAY 99
- d. AR 40-68, Quality Assurance Administration, 20 DEC 89
- e. MEDCOM Reg 40-41, The Patient Safety Program, 14 JAN 02
- f. WRAMC Reg 40-25, Governing Body and Medical Staff Bylaws, 1 OCT 98
- g. WRAMC Reg 40-92, Committees, Boards, and Councils, 1 SEP 99
- h. Accreditation Manual for Hospitals, Ambulatory Care, and Behavioral Care, Joint Commission on Accreditation of Healthcare Organizations.

3. Applicability. This regulation is applicable to all clinical departments and service, inpatient and outpatient, and to all administrative and support area of the Walter Reed Army Medical Center. It is also applicable to contract employees and volunteers providing care for the Walter Reed Army Medical Center (WRAMC).

4. Terms. Terms used in and applicable to Performance Improvement and Patient Safety are listed in Appendix A.

5. Responsibilities.

- a. The Commander of the Walter Reed Army Medical Center has the ultimate responsibility for establishment of policy and standardized procedures to improve organizational performance and facilitate the safe delivery of quality health care to all categories of beneficiaries and meets that responsibility by:
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* This regulation supersedes WRAMC Regulation 40-68, 1 March 1999
WRAMC Reg 40-68

(1) Providing the leadership and support necessary to provide high quality, safe, cost-effective patient care. This includes the designation of a Director for the Patient Safety Program.

(2) Ensuring trained, caring, and competent staff members are available to meet customers needs and expectations.

(3) Requiring assessment activities that adequately scrutinize the safety, appropriateness, efficiency and efficacy of the health care services provided.

b. The Deputy Commander for Clinical Services (DCCS) will:

(1) Serve as the Chairperson for the Quality Outcomes/Risk Management Committee.

(2) Enforce Department of Defense Directives, Army Regulations and local guidance regarding Performance Improvement and Patient Safety.

(3) Forward to the Commander, through the Executive Committee of the Medical and Administrative Staff, the recommendations for actions from the Quality Outcomes/Risk Management Committee.

(4) Oversee implementation of the Performance Improvement Program in all clinical areas.

(5) Act as or appoint a Medical Advisor to the Performance Improvement Office to aid in working with the Medical Staff and provide advice on planning and implementing change.

(6) Monitor and evaluate clinical processes.

c. The Deputy Commander for Administration will:

(1) Manage the performance improvement of the organization's governing activities, administrative activities and support activities.

(2) Provide for assessment of competence of all non-clinical employees.

(3) Manage administrative/support issues as they relate to Performance Improvement.

(4) Oversee implementation of the Performance Improvement Program in all administrative and support areas.

d. The Deputy Commander for Nursing will:

(1) Manage the nursing aspects of Performance Improvement throughout the organization.

(2) Provide for assessment of competence of all nursing employees.

(3) Manage nursing issues as they relate to Performance Improvement.

(4) Oversee implementation of the nursing aspects of the Performance Improvement/Patient Safety Program in all clinical areas.

e. Walter Reed Army Medical Center Performance Improvement Director will:

(1) Provide the overall support in developing and implementing the Performance Improvement Plan in collaboration with the Command and Clinical and Administrative Staffs.

(2) Serve as the command expert regarding requirements of Army regulations and DoD directives pertaining to Performance Improvement and the Accreditation Manual for Hospitals.

(3) Produce an agenda for each Quality Outcomes/Risk Management Committee meeting and provide a recorder for taking of the minutes.

(4) Serve as custodian of plans, reports, minutes and correspondence from departments and standing committees.

(5) Maintain liaison with the Joint Commission on Accreditation of Healthcare Organizations.

(6) Organize and coordinate the review of the Performance Improvement Program and Plan.

(7) Serve as the subject matter expert of the Risk Management Program, to include sentinel events and other patient safety events as outlined in Appendix B.

(8) Serve as Chairman of the Performance Improvement/Risk Management/Patient Safety Advisory Group. This group will meet daily to review incident reports, patient safety and risk management issues. Other members include Patient Safety Director, Judge Advocate Claims Officer, Performance Improvement Nursing Coordinator, Pharmacy Representative, Clinical Engineering Quality Improvement Representative, Laboratory Representative, and a physician from department/service on a rotating basis, in addition to other members of the Performance Improvement Office Staff.

(9) Serve as a member of the Patient Safety Committee.

(10) Oversee the Continuous Performance Improvement Training program.

f. Director, Patient Safety Program will:

(1) Coordinate the WRAMC Patient Safety Program and serve as chairperson of the interdisciplinary Patient Safety Committee.

(2) Exercise broad oversight and collaborate with various key staff to ensure the effective integration patient safety functions by the organization

(3) Provide expertise and guidance to staff members in the areas of risk assessment, prospective analyses, aggregate analyses, Root Cause Analysis and the development and evaluation of action plans.

(4) Coordinate and facilitate the education of all WRAMC-assigned personnel and beneficiaries on Patient Safety.

(5) Ensure that both WRAMC staff and beneficiaries are surveyed periodically, according to current DoD guidance, to determine their perceptions of the Patient Safety climate within their health care organizations, utilizing the tool the United States Army Medical Command (USAMEDCOM) supplies.

(6) Implement a process to receive and centrally manage all Patient Safety event reports from clinical and administrative staff and/or patients and families.

WRAMC Reg 40-68

Maintain the Patient Safety database and submit information and reports regarding Patient Safety events, Root Cause Analyses, action plans, and aggregate data to the WRAMC Patient Safety Committee and USAMEDCOM.

(7) Acknowledge the receipt of Patient Safety reports (WRAMC Form 1811 and DA Form 4106) and provide timely feedback to staff members who submit Patient Safety reports and/or plans for process/system improvements.

(8) Oversee the investigation of all Sentinel Events to ensure coordination of all data collection activities, completion of a thorough and credible Root Cause Analysis, development of an action plan, and required reporting through channels to the appropriate agencies.

(9) Ensure that Patient Safety action plans are implemented, evaluated for effectiveness, and communicated both internally and to the appropriate external organizational entities.

(10) Review, aggregate, and analyze reports of all close calls, near misses, adverse events, and Sentinel Events--to include written findings and recommendations for improvements in systems and processes to reduce the frequency and severity of patient harm.

(11) Provide the Patient Safety Committee, as well as all levels of staff, information regarding WRAMC, corporate, and nationwide Patient Safety alerts, updates, and initiatives.

(12) Present opportunities for improvement related to organizational risk assessment(s), with recommendations for identified risks, implementation plans, and follow-up activities to the WRAMC Patient Safety Committee and USAMEDCOM for action.

(13) Ensure effective feedback to appropriate personnel on lessons learned and process/system improvements that have been or will be initiated.

g. The WRAMC Safety and Occupational Health Manager will serve as a voting member on the Patient Safety Committee and serve as an active Patient Safety Team participant.

h. Department Chiefs, Separate Service Chiefs, and Directors will:

(1) Have responsibility for Performance Improvement and Patient Safety activities in their departments/separate services. Authority to perform these activities may be delegated to an appointed Performance Improvement Coordinator and/or Team Leader.

(2) Review plans, reports, and correspondence of the department/separate services Performance Improvement/Patient Safety activities with a focus on interdisciplinary Performance Improvement activities.

(3) Designate a qualified health care professional to inform the patient or family member(s) when a Patient Safety event results in an unanticipated outcome of care.

(4) Promote support/assistance to staff members involved in Sentinel Events.

i. Performance Improvement Coordinators of departments, services and directorates will:

(1) Chair meetings of the Departmental Quality Outcomes Committee.

(2) Coordinate the design and performance of at least one project per year to improve organizational performance.

This performance improvement project will require multi-disciplinary participation, it must be improvement focused, measurable, and outcomes must be included. The projects need to consider the full continuum of care to focus on a spectrum of measurable outcomes as outlined in Appendix C. The Quality Outcomes/Risk Management Committee can direct that a specific project be initiated on a particular improvement process when it is in the best interest of the Walter Reed Army Medical Center to do so. This may be an area of high risk, high cost or where there is demonstrated need to improve outcomes. The Quality Outcomes/Risk Management Committee will also direct the available resources/energies when needed during the project. An annual report will be required to be presented to the Quality Outcomes/Risk Management Committee on the project undertaken.

(3) Review reports on invasive procedures from services and advise action on outlier data.

(4) Represent Department as a member of the Quality Outcomes/Risk Management Committee.

(5) Ensure that peer review is performed on credentialed providers and that this information is available for the Department/Service Chief's review. Peer review will be included in medical record reviews at least quarterly, incorporating at least 5% or 30 records per quarter, whichever is greater.

j. All personnel:

(1) Fully understand and take responsibility for their own roles in performance improvement and patient safety.

(2) Actively participate in creating a safe environment for themselves, peers, patients, and families by meeting organizational and professional standards, following identified best/safe practices, and proactively mitigating unsafe conditions or situations.

(3) Complete organization/unit-based orientation and participate in ongoing patient safety education

(4) Voluntarily report all close calls/near misses, adverse events, and/or Sentinel Events.

(5) Initiate immediate steps to ensure patient and staff safety and secure any supplies/equipment that may have precipitated a Patient Safety event.

(6) Educate patients/families in their roles and responsibilities to facilitate the safe delivery of care.

(7) Remain informed of recommended successful best/safe practices and safety alerts.

k. The Executive Committee of the Medical and Administrative Staff will:

(1) Receive and act on reports and recommendations from both the Quality Outcomes/Risk Management Committee and the Patient Safety Committee.

(2) Determine the qualifications and competence of all personnel.

(3) Continuously uses the information from data analysis to identify system changes that will improve performance or improve patient safety

(4) Maintain quality control programs as required.

l. The Quality Outcomes Committee will:

WRAMC Reg 40-68

- (1) Oversee the implementation of the Walter Reed Army Medical Center's Performance Improvement/Patient Safety/Risk Management Plan.
- (2) Receive, review and act upon plans and reports from the Performance Improvement activities throughout the hospital.
- (3) Receive briefings and review reports from the standing committees in the Walter Reed Army Medical Center as detailed in WRAMC Regulation 40-92.
- (4) Integrate and coordinate Performance Improvement, Patient Safety and Risk Management findings so that opportunities to improve patient care services are identified, acted upon and re-evaluated in a comprehensive manner.
- (5) Require all functional elements and Performance Improvement Teams to report on their Performance Improvement initiatives on a regular basis.
- (6) Receive and review reports from the functional elements, Performance Improvement Teams and clinical committees which address performance improvement activities. Consider their recommendations and reports and forward to the Executive Committee of the Medical and Administrative Staff.

m. The Patient Safety Committee will:

- (1) Have a multidisciplinary membership to include, as a minimum, the Director of the Patient Safety Program (who serves as chair), the Performance Improvement Director and staff, representatives from Department of Pathology and Area Laboratory Services, Logistics, Pharmacy, the Hospital Safety Officer, Office of the Staff Judge Advocate Representative, Department of Nursing representatives (to include nursing performance improvement), the patient representative and two physicians representing high risk areas (critical care and surgery.)
- (2) Review Patient Safety surveys and prioritize needs.
- (3) Choose 1 high-risk process and evaluate prospectively. Other high-risk processes will be prioritized and completed if resources are available.
- (4) Follow all patient safety initiatives; Provide expertise for investigations.
- (5) Provide metrics to the Army Medical Command (MEDCOM).
- (6) Provide minutes that will summarize Patient Safety activities to include, as a minimum aggregation and analyses of all clinical and non-clinical-reported events, trends, and lessons learned, actions necessary for organizational process/system improvements, as appropriate, proactive Patient Safety error reduction activities, and progress related to organizational risk assessments, prospective analyses, and RCA action plan implementation and effectiveness, according to established timelines.
- (7) Provide education for staff and consultation for patient safety issues.
- (8) Forward minutes to the Executive Committee of the Medical and Administrative Staff (ECMAS) and the Quality Outcomes Committee (QOC). Recommendations will be considered and prioritized with other organizational system/process improvement actions, as appropriate.

- n. Utilization Management: Utilization Management and Quality Management are inextricably woven together and need to be linked together and be a part of the continuum of care.

Utilization Management supports outcomes with data as necessary and provides the most timely data to the command, department/service chiefs, and others as needed.

Utilization Management is part of the performance improvement process and reports to the Quality Outcomes Committee.

6. Policies. All Walter Reed Army Medical Center departments, services, and directorates will conform to Performance Improvement standards as outlined in the current manual of the Joint Commission on Accreditation of Healthcare Organizations. See standards listed in Appendix D.

7. Procedures.

a. Managing quality requires 3 processes. These are:

(1) Quality Planning/Process Design.

(a) Establish the infrastructure.

(b) Determine customer's needs, expectations and professional standards.

(c) Develop practices that respond to the customer's needs and expectations.

(d) Develop processes to produce the desired outcome.

(2) Quality Control/Internal Monitoring as prioritized at the department/service level but at least in the functions of Laboratory Services, Diagnostic Radiology Services, Dietetic Services, Nuclear Medicine Services, Radiation Oncology Services, Medication Use, Blood and Blood products, Operative and Invasive Procedures, and Utilization Management.

(a) Evaluate actual performance.

(b) Compare actual performance to product goals.

(c) Act on the difference.

(3) Performance Improvement.

(a) Identify the improvement projects.

(b) Provide the staff with resources, training, and motivation to plan and develop changes.

(c) Implement change and monitor the outcome.

(d) If issues are identified in the process, involving many functional elements, refer them to the Performance Improvement Council for review and establishment of an installation-wide Process Action Team.

b. Data that the organization considers for collection to monitor performance include the following:

(1) Performance measures related to accreditation and other requirements.

(2) Risk Management.

WRAMC Reg 40-68

(3) Utilization Management

(4) Quality Control

(5) Patient, family and staff opinions, needs, perception of risks to patients, and suggestions for improving patient safety.

(6) Staff willingness to report medical/health care errors.

(7) Staff opinions and needs.

(8) Outcomes of processes or services.

(9) Autopsy results, when performed.

(10) Customer demographics and diagnoses.

(11) Financial data.

(12) Infection control surveillance and reporting.

(13) Research data.

(14) The appropriateness and effectiveness of pain management.

c. Problem-Solving Model. The Walter Reed Army Medical Center uses the FOCUS-PDCA Process Improvement Model to direct a systematic, statistical-based quality control method for improving processes. This approach to problem solving is used by all Process Action Teams and recommended for use at all levels. FOCUS-PDCA is as follows:

- | | |
|-----------------------------------------------|-------------------------------------------|
| F - Find a process to improve. | P - Plan the improvement. |
| O - Organize a team that knows the process. | D - Do the improvement (pilot test). |
| C - Clarify current knowledge of the process. | C - Check the results of the improvement. |
| U - Understand the cause or variations. | A - Act to hold the gain. |
| S - Select the process to improve. | |

8. Background.

a. The Accreditation Manual for Hospitals, Ambulatory Care and Behavioral Health Care completes the transition of standards from a focus on capability, to a focus on actual performance of clinical and organizational functions and processes, which most significantly impact on the safety and quality of patient care and services. These changes provide a standards-based evaluation process to provide for measurement, assessment, outcomes, and performance improvement.

b. What must be measured? The minimal requirements are those important aspects of care and services as identified in the Accreditation Manual for Hospitals, Ambulatory Care, Behavioral Health Care and AR 40-68. Examples would be blood usage, medication use, falls, restraint use, staffing effectiveness, and operative and other invasive procedures.

c. **Core Measures-The Next Phase of ORYX** - A planned component of the ORYX initiative is the identification and use of core measures.

These are standardized performance measures that can be applied across accredited health care organizations in a particular accreditation program.

The Joint Commission on the Accreditation of Healthcare Organization's (JCAHO) intent is to identify, rather than develop, sound measures that support both the objectives of the ORYX initiative and organizational process improvement. Initial core measure sets will be selected by June 30, 2002 and data collection on selected core measure sets will begin for July 2002 discharges. JCAHO has selected four core measures, and the organization will select two, and measure performance utilizing the JCAHO pre-selected measure sets. The Joint Commission will be informed of the system chosen and measures selected.

d. **Staffing effectiveness** - The institution will select a minimum of four screening indicators, two clinical/service and two human resource indicators to assess staffing effectiveness. The focus is on the relationship between human resource and clinical/service screening indicators, with the clear understanding that no one indicator, in and of itself, can directly correlate with staffing effectiveness.

(1) Examples of clinical/service screening indicators are medication errors and falls.

(2) Examples of human resource screening indicators are overtime and staff vacancy rate.

(3) Staffing is defined as the number, competency, and skill mix of staff related to the provision of needed services.

9. Confidentially Statement.

a. The National Defense Authorization Act, Title 10, United States Code, Section 1102, provides that records created by or for the Department of Defense in a medical or dental quality assurance program are confidential and preclude disclosure of or testimony about the records or about any of the findings, recommendations, evaluations, opinions or actions taken by the quality assurance activity expert in limited situations. These records include any proceedings, minutes, reports or other activities that are produced or compiled by a DoD activity, as part of a medical quality assurance program. The statutory privilege is designed to improve the quality of medical care by encouraging a thorough and candid medical peer review process. AR 40-68 carries a complete explanation of the provisions of this law, to include penalty provisions from a \$3,000 fine for first offense to \$20,000 for subsequent violations. To ensure identification of Quality Assurance or Performance Improvement documents, the following shall be typed or stamped on the lower right hand section of the first page of each document:

IAW TITLE 10 U.S.C. 1102, THIS DOCUMENT, PRODUCED FOR
QUALITY ASSURANCE PURPOSES, IS PROTECTED AGAINST DISCLOSURE.
UNAUTHORIZED DISCLOSURE CARRIES A \$3000 FINE.

b. When the Quality Assurance or Performance Improvement records are subpoenaed, or requests are received through the Freedom of Information Act, all records maintained for these purposes are not released.

APPENDIX A

LIST OF TERMS

Accreditation - A determination by the Joint Commission that an eligible organization complies with applicable Joint Commission standards.

Accreditation Manual for Hospitals and Accreditation Manual for Ambulatory Care - A publication of policies and procedures relating to hospital accreditation surveys and the delineation of current hospital and ambulatory care standards and corresponding scoring guidelines.

Accreditation Survey - An evaluation of an organization to assess its level of compliance with applicable Joint Commission standards and to make determinations regarding its accreditation status.

Action plan - The end product of a Root Cause Analysis that identifies the risk reduction strategies the organization intends to implement to prevent the recurrence of similar adverse events in the future.

Actual event - A situation or circumstance that did occur either with or without harm to the patient.

Adverse event - An adverse event is an occurrence or condition associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Patient safety events such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

Aggregate - To combine standardized data and information collected over time.

Aggregate review - The process of analyzing recurring incidents, events, or close calls (near misses) for trends and patterns. This information is utilized by the organization for process improvement interventions.

Assess - To transform data into information analyzing it.

Assessment - The systematic collection and review of patient specific data.

Benchmark - A point of reference or standard by which something can be measured, compared, or judged, as in benchmarks of performance.

Bylaws - A governance framework that establishes the roles and responsibilities of a body of its members.

Close call - A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur more frequently than actual adverse events, proactive analysis of close calls provides tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

Contributing factors - Additional reasons, not necessarily the most basic reasons, for an event to be less than ideal, as planned, or as expected. Contributing factors may apply to individuals, systems operations, or the entire organization.

Core measures - Standardized performance measures that can be applied across health care accreditation programs. These measures are comprised of precisely defined data elements, calculation algorithms, and standardized data collection protocols based on uniform medical language.

Criteria - Expected level of achievement, or specifications against which performance or quality may be compared

Data - Material facts or clinical observations that have not been interpreted.

Dimensions of Performance - Nine definable, measurable, and improvable attributes of organization performance related to "doing the right things right" and "doing things well" using the below listed model:

1. **Efficacy:** of the procedure or treatment in relation to patient's condition. The degree to which the care/intervention used for the patient has been shown to accomplish the desired/projected outcome.
2. **Appropriateness:** of a specific test, procedure, or service to meet the patient's needs. The degree to which the care/intervention provided is relevant to the patient's clinical needs, given the current state of knowledge.
3. **Availability:** of a needed test, procedure, treatment, or service to meet the patient's needs. The degree to which the appropriate care/intervention is available to meet the needs of the patient served.
4. **Timeliness:** with which a needed test, procedure, treatment, or service is provided to the patient. The degree to which the care/intervention is provided to the patient at the time it is most beneficial or necessary.
5. **Effectiveness:** with which tests, procedures, treatments, and services are provided. The degree to which the care/intervention is provided in the correct manner, given the current state of knowledge, to achieve the desired/projected outcome for the patient.
6. **Continuity:** of the services provided to the patient with respect to other services, practitioners, and providers, and over time. The degree to which the care for the patient is coordinated among practitioners, between the organizations, and over time.
7. **Safety:** of the patient and others to whom the services are provided. The degree to which the risk of an intervention and the risk in the care environment are reduced for the patient and others, including the health care provider.
8. **Efficiency:** with which services are provided. The relationship between the outcomes and the resources used to deliver patient care.
9. **Respect and Caring:** with which services are provided. The degree to which a patient, or designee, is involved in his or her own decisions and to which those providing services do so with sensitivity and respect for the patient's needs, expectations, and individual differences.

WRAMC Reg 40-68

Evaluation - Analysis of collected, compiled, and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be acceptable or unacceptable; and problems or opportunities to improve care are identified.

Failure Mode and Effect Analysis (FMEA) - Prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome. A systematic approach to identify and prevent product and process problems before they occur.

Function - A goal-directed, interrelated series of processes, such as patient assessment or patient care or psychological and physiological processes of an organ, body part, person, and/or system that enable the individual to perform activities associated with living, learning, and/or work.

Governing Body - The individuals, group, or agency that has ultimate authority and responsibility for establishing policy, maintaining quality of care, and providing for organizational management and planning.

Gross negligence - See Reckless conduct.

Intentional unsafe act - Any alleged or suspected deliberate act or omission by a provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves--a criminal act; a purposefully unsafe act; patient abuse; or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, the military or civil service disciplinary systems, or an administrative investigation, and are not within the definition of an adverse event.

Joint Commission on Accreditation of Healthcare Organizations - An independent, not-for-profit organization, dedicated to improving the safety and quality of care in organized health care settings. The major functions of the Joint Commission include developing organizational standards, awarding accreditation decisions, and providing education and consultation to health care organizations.

Measure - To collect quantifiable data about a dimension of performance of a function or process.

Measurement - The systematic process of data collection, repeated over time or at a single point in time.

Near miss - An event or situation that could have resulted in harm to a patient but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "close call" incidents.

ORYX - A JCAHO initiative that integrates outcomes and other performance measurement data into the accreditation process.

Outcome - The result of the performance (or non-performance) of a function or process.

Patient safety event - An incident or error that occurred (actual event), or almost occurred (close call/near miss), that caused, or had the potential for causing, harm to a patient.

Performance Improvement - The continuous study and adaption of functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of patients and other users of

services.

Performance Measure - A measure, such as a standard or indicator, used to assess the performance of a function or process of any organization. A quantitative tool (for example, rate, ratio, index, percentage) that provides an indication of an organization's performance in relation to a specified process or outcome.

Process - A goal-directed, interrelated series of actions, events, mechanisms, or steps. A systematic series of actions directed to the achievement of a goal.

Process Action Team - Process action teams are cross-functional teams, comprised of process owners and subject matter experts. They collect data on process performances and apply statistical methods for analysis. They implement process improvements.

Quality - Quality is both the customer's perception of the product, service or information provided and the supplier's knowledge of customer requirements, variation between customers and applicable standards.

Quality improvement - An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of individuals and others. Synonyms include continuous quality improvement, continuous improvement, organization-wide performance improvement, and total quality management.

Rape - Sexual intercourse by a person, executed by force and without consent of the victim. It may be committed on a victim of any age. Any penetration, however slight, is sufficient to complete the offense. "Any person subject to this chapter who commits an act of sexual intercourse by force or without consent, is guilty of rape." (Article 120, Uniform Code of Military Justice).

Reckless conduct - Involves conscious disregard of risk. Also referred to as gross negligence. Reckless conduct differs from "negligent conduct" in intent. Negligence is the failure to recognize a risk that should have been recognized while reckless conduct is a conscious disregard of a known risk. NOTE: The legal definitions may vary slightly.

Risk assessment - A method used to proactively evaluate the probability of a patient safety event in order to minimize the risk of the event actually occurring.

Risk management - Clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims.

Root cause - The most basic reason that a situation did not turn out ideally, as planned, or as expected.

Root cause analysis - A process for identifying the basic or contributing causal factor(s) associated with an adverse event or close call. The review is interdisciplinary and includes those who are closest to the process. It focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed, and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls.

Root cause analysis team (RCAT) - The group identified by the commander to develop the Root Cause Analysis and Action Plan. The RCAT should include leaders of performance improvement/Quality Management, Risk Management, nursing and patient care services; the medical staff; the department head or

WRAMC Reg 40-68

supervisor of the area in which the event occurred; administrative staff (e.g., Deputy Commander for Administration (DCA), Risk Manager (RM), facility safety); a Staff Judge Advocate representative; and others as necessary depending on the event. RCAT members will be trained and knowledgeable in the Sentinel Event process.

Safety assessment code (SAC) matrix - A risk assessment tool that considers the severity of an adverse or near miss event together with the probability of the event's recurrence. The score, or SAC, assigned to the event determines the type of action that should be taken to address the event (i.e. Root Cause Analysis, intense analysis, or no action). See appendix

Sentinel event - An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof that is not related to the natural course of the patient's illnesses or underlying condition. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

Significant medication errors and significant adverse drug reactions - Unintended, undesirable, and unexpected effects of prescribed medications or of medication errors that require discontinuing a medication or modifying the dose; require initial or prolonged hospitalization; result in disability; require treatment with a prescription medication; result in cognitive deterioration or impairment; are life threatening; result in death; or result in congenital anomalies.

Staffing effectiveness - The number, competency, and skill mix of staff related to the provision of needed services.

Standard - A statement of expectation that defines the structures and processes that must be substantially in place in an organization to enhance the quality of care.

Unanticipated Outcome - A result that differs significantly from what was anticipated to be the result of a treatment or procedure.

APPENDIX B

PATIENT SAFETY/RISK MANAGEMENT PROGRAM/SENTINEL EVENTS

1. Patient Safety (PS) and Risk Management (RM) involve a variety of clinical and administrative activities that identify, evaluate, and reduce the potential for harm to beneficiaries, visitors and personnel. While both PS and RM include elements of risk identification, risk assessment, and risk reduction or containment, the frame of reference for patient safety is different.
2. PS activities are pro-active and focus on reducing or avoiding misadventures during the delivery of medical/health care to beneficiaries. Emphasis is placed on improving medical systems and processes in order to prevent harm related to interventions and to modify, reduce or eliminate exposure to risk whenever possible. This program is meant to be non-punitive, and interdisciplinary, focusing on system and process design, rather than on the individual involved in a Patient Safety mishap.
3. The objectives of the Risk Management Program are to promote the provisions of safe, high quality care, and to continuously improve the levels of safety and thus the quality of care provided. This program provides for the reduction of claims cost and other financial losses, and for accident and injury prevention. All events that present risks to patients will be evaluated regardless of the potential for financial loss to the institution.
4. The risk management/patient safety program has four key functions. These include:
 - a. Identify general clinical and administrative areas that represent actual or potential sources of patient injury.
 - b. Identify and evaluate individual cases of undesirable or adverse occurrences/outcomes within all areas of the Walter Reed Army Medical Center. Inpatient occurrence screening will be done on discharge and instructions are at Appendix E.
 - c. Resolution of problems through data evaluation.
 - d. Provide for peer review of cases when needed.
5. To coordinate the four key functions and accomplish this goal, the Walter Reed Army Medical Center activities will:
 - a. Upon identification of an actual Patient Safety event, the staff member will immediately perform necessary health care interventions to protect and support the patient's clinical condition. The patient's attending physician and other physicians, as appropriate, will be contacted as soon as possible to report the incident and to provide an update on the patient's current clinical status. As appropriate to the event, the staff member will initiate all physician-directed orders and take other necessary health care interventions to contain the risk to others, and to preserve event-related materials that may require further investigation. Examples of physical information preservation include: removal and preservation of a

blood unit for a suspected transfusion reaction; preservation of intravenous (IV) tubing, the fluid bag, and/or IV pump for a patient with a severe drug reaction from IV medication; and all medical equipment involved in an incident will be immediately taken out of service and quarantined. Preservation of information also includes documenting the facts regarding the event in the patient's medical record according to organizational policy and procedure.

WRAMC Reg 40-68

b. If the Patient Safety event involves serious physical or psychological injury, unexpected death, or qualifies as a Sentinel Event that is reviewable by the JCAHO, the appropriate department/service chief and the nursing supervisor will be notified immediately. If such Patient Safety events occur after hours, the administrative officer of the day will also be notified immediately. Individuals notified will ensure proper notification of designated members of the Military Treatment Facility (MTF) senior leadership.

c. Any individual in any department who identifies a potential (e.g., close call) or actual Patient Safety event will immediately notify his or her supervisor and will initiate an incident report (WRAMC Form 1811 or DA Form 4106). This report will contain concise, factual, objective, and complete details about the event. While explanation of the event is appropriate to include precipitating circumstances or reasons, speculation about factors that contributed to the event should be avoided. Incident reports will be forwarded to the staff member's unit, clinic, and/or department manager, as appropriate, within 24 hours of discovery of event or on the first duty day following a weekend or holiday. The manager/supervisor will review the document, add any additional relevant information, and forward it to the Performance Improvement Office within 24 hours of receipt.

d. The Performance Improvement/Risk Management/Patient Safety Advisory Group will review all incident reports and assign a severity category (SAC) (appendix C). The Risk Manager will assess events from a reactive performance review perspective, whereas the patient safety director assesses events from a pro-active, systems approach, with no assessment of an individual's performance or blame attached to the investigation. In addition, the Director of Performance Improvement and the Director of Patient Safety will determine what specific actions are necessary to further evaluate SAC 2 events. If the Patient Safety event is a SAC 3, the Director of Patient Safety will immediately notify the WRAMC commander and a root cause analysis team (RCAT) will be chartered. The Director of Patient Safety will also enter the information from the incident report into the WRAMC Patient Safety database. If a Patient Safety event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event shall be reported to the appropriate authorities for investigation. Some events fall within the definition of both an adverse event and an intentional unsafe act. For example, an infant abduction would be both a crime and a JCAHO-reportable sentinel event that requires a Root Cause Analysis (RCA). In cases that appear to be both an adverse event and an intentional unsafe act, primary authority and responsibility for dealing with the event belongs to the commander and risk manager. The Director of Patient Safety will coordinate a review of the systems and processes implicated in the actual or potential intentional unsafe act, to include conducting an RCA, if applicable, but will defer to the separate command investigation with respect to the culpability of any person involved in the event.

e. External reporting requirements. All incidents meeting the definition of a Sentinel Event must be reported to the USAMEDCOM, and those events that meet the criteria for review by the JCAHO will be appropriately reported to that organization. External reporting of the Patient Safety event is the responsibility of the WRAMC Commander (or his/her designee) and includes notification of USAMEDCOM Patient Safety Committee within 72 hours of identification of the event. The MTF will also electronically notify its Regional Medical Command (RMC) of the occurrence of a Sentinel Event (SE). All Sentinel events that are reviewable by the JCAHO, must be reported to the JCAHO within 5 working days of the identification of the event. The appropriate documentation as required in current JCAHO guidance

(http://www.jcaho.org/sentinel/se_form.html) will be completed and forwarded by facsimile transmission or commercial overnight delivery service to the JCAHO Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181. No patient or caregiver identifiers will be used when reporting a Sentinel Event to the JCAHO.

f. In cases requiring medical review due to the possibility that this may become a potentially compensable events, the case history shall be prepared and forwarded to the Patient Care Assessment

Committee for review as outlined in WRAMC Regulation 40-92.

g. Informal investigations will be completed on an as needed basis by the patient safety/risk management staff.

h. For formal investigations, the DCCS or Commander will appoint an investigating officer to complete an investigation in accordance with AR 15-6.

i. An RCA must be conducted and an action plan completed for all actual SAC 3 Patient Safety events and those that meet the definition of a SE. The WRAMC commander, in consultation with the DCCS, DCN, Director, Performance Improvement and Director of the Patient Safety Program, will designate and formally charter an RCAT to conduct a thorough and credible RCA. The Performance Improvement Director and a legal advisor from the OCJA will be notified of all sentinel events and may participate in the process of conducting the RCA, if appropriate. The RCAT will conduct the RCA according to current USAMEDCOM guidance to facilitate standardization of data element collection and event analysis across the Military Health Care System (MHS).

(1) An RCA is the process for identifying the basic and/or contributing causal factor(s) associated with Patient Safety events. The review is interdisciplinary and includes those who are closest to the process, but typically not those directly involved in the specific event. (Note: Those individuals directly involved in the event will be consulted for event-related information.) The RCA focuses on systems and processes, not individual performance. The analysis asks “what” and “why” until all aspects of the process are reviewed and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and to reduce the risk of adverse events, or the recurrence of close calls, with the ultimate goal of reducing and/or eliminating patient harm.

(2) RCA action plan. Once the RCA has been completed, a detailed action plan must be developed to enumerate the risk reduction strategies that the organization intends to implement to prevent the recurrence of similar events. The action plan should address responsibility for implementation, oversight, pilot testing (if appropriate), timelines, and the specific metrics to be employed in evaluating the effectiveness of the actions taken.

(a) RCA and action plan review. The RCA and associated action plan for a Sentinel Event will be submitted for review as follows: (1) By the USAMEDCOM-a copy of the completed RCA and the action plan will be provided to the USAMEDCOM Patient Safety Committee (PSC) within 45 calendar days of the MTF’s discovery of the occurrence of an SE. Commercial overnight delivery service is authorized for this purpose. (2) By the JCAHO per USAMEDCOM guidance.

(3) Action plan follow-up review. Six months following the RCA submission, a follow-up after action report that addresses the effectiveness of the improvements implemented by the organization will be forwarded to the USAMEDCOM PSC, Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010. A copy will be provided to the JCAHO, Office of Quality Monitoring, 1

Renaissance Boulevard, Oakbrook Terrace, IL 60181.

j. All other incidents are trended to the appropriate departments and services for their information and follow-up, and tracked by the Patient Safety Committee.

6. The WRAMC Form 1811 and DA Form 4106 have provided an effective method of identifying and reporting incidents or potential risk circumstances, regardless of whether or not those incidents are considered compensable and provide for reporting of information in accordance with the Safe Medical Devices Act.

17

WRAMC Reg 40-68

7. In cases involving an unanticipated outcome of care, a qualified health care provider will inform the patient and/or his/her family member(s). This information is provided as a matter of policy and does not affect any rights or obligations in legal or administrative proceedings. Under no circumstances will QA-protected information be released or provided to the patient/family member.

(1) The MTF commander, or designee, is responsible to ensure that provider and patient/family member communication takes place. To ensure continuity, the initial disclosure of information and subsequent discussions with the patient and/or family should be handled, whenever possible, by the primary care manager or attending physician responsible for the patient's overall care. During the initial communication, and at subsequent planned discussions, at least one other hospital staff member should be present. For discussions anticipated to be complex or difficult, the patient/family member may have another individual with them for support. The designated primary communicator will document in the patient's medical record what was communicated to the patient/family, the patient/family member's response, and any other pertinent discussion.

(2) In most cases, facts surrounding the patient safety event that affect the patient can and should be disclosed to the patient/family member by the provider.

(3) Any specific questions relative to disclosure of information associated with unanticipated adverse outcomes should be referred to the MTF Office of the Staff Judge Advocate.

8. Definitions:

a. An **incident** is any happening or event which is not consistent with routine care of a patient, or an unforeseen circumstance which involves patients, visitors, or staff.

b. A **potentially compensable event** is a breach of the standard of care which occurs with injury or dissatisfaction of the patient or patient's family.

c. A **medication error** is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care organization, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labeling; packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

d. **Close call/near miss.** A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur more frequently than actual adverse events, proactive analyses of close calls provide a tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for

reporting these opportunities for improvement.

d. An **adverse event** is an occurrence associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

e. An **unanticipated outcome** is a result that differs significantly from what was anticipated to be the result of a treatment or procedure.

18

WRAMC Reg 40-68

f. An **occurrence** is any accident or event not consistent with patient care that either did or could result in an injury to a patient.

g. A **Sentinel Event** is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization. Occurrences that are subject to review by the Joint Commission under the sentinel event policy are as follows:

(1) The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition.

(2) The event is one of the following (even if the outcome was not death or major permanent loss of function):

(a) Suicide of a patient in a setting where the patient receives around-the-clock care.

(b) Infant abduction or discharge to the wrong family.

(c) Rape

(d) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(e) Surgery on the wrong patient or wrong body part.

h. **Inpatient Occurrence Screening** is done through a checklist in the inpatient medical record. The Chairperson of the Patient Care Assessment Committee will be responsible for reviewing all positive inpatient occurrence screens and forwarding them to the full Patient Care Assessment Subcommittee for peer review when appropriate. The process, content, and instructions for completing the Inpatient Occurrence Screening Checklist are outlined in Appendix F.

9. Any staff member who is aware of, or has knowledge of a patient safety event, in which it is reasonably suggested there is probability that an event has caused or could have caused injury or illness to staff, patients, or visitors, must report using the WRAMC Form 1811 or DA 4106 and forward to the Risk Management Office.

APPENDIX C

Patient Safety Program
Safety Assessment Code Matrix

Severity Categories

Catastrophic	Major
Patients with actual:	Patients with actual:
<p>Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient' s illness or underlying condition (i.e., acts of commission or omission). Suicide (inpatient or outpatient).</p> <p>Rape.</p> <p>Hemolytic transfusion reaction.</p> <p>Surgery/procedure on the wrong patient or wrong body part.</p> <p>Infant abduction or infant discharge to the wrong family.</p> <p>Death or major permanent loss of function that is a direct result of injuries sustained in a fall, or associated with an unauthorized departure from an around-the-clock treatment setting, or the result of an assault or other crime.</p> <p>Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient' s illness or underlying conditions (i.e., acts of commission or omission).</p> <p>Disfigurement.</p> <p>Surgical intervention required.</p> <p>Increased length of stay or level of care of 3 days</p>	<p>Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient' s illness or underlying conditions (i.e., acts of commission or omission).</p> <p>Disfigurement.</p> <p>Surgical intervention required.</p> <p>Increased length of stay or level of care of 3 days or more.</p>

or more.	
Moderate	MINOR
Patients with actual:	Patients with actual:
Increased length of stay or higher level of care for less than 3 days.	No increased length of stay or increased level of care.

Probability of Recurrence

Like the severity categories, the probability of recurrence applies to actual adverse events and close calls.

In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

High - Likely to occur immediately or within a short period of time.

Medium - Likely to occur several times in 1 to 2 years.

Low - May happen at intervals greater than 2 years.

PROBABILITY	SEVERITY			
	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

How The SAC Matrix Works

When a severity category is paired with a probability category for either an actual event or close call, the result is a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or SACS, can then be used for comparative analyses and for deciding who needs to be notified about the event.

Notes

1. All known reporters of events, regardless of SAC score (1, 2, or 3) will receive appropriate and timely feedback.
2. The Patient Safety Manager (or designee) will refer adverse events or close calls (related solely to staff, visitors, or equipment/facility damage) for assessment and resolution to relevant facility experts or services on a timely basis.
3. A quarterly aggregated analyses may be used for two types of calls (this includes all events or close calls other than actual SAC 3s since all actual SAC 3s require an individual RCA). These two types are falls and medication errors. The use of aggregated analyses serves two important purposes. First, greater utility of the analyses (i.e., trends or patterns not noticeable in individual case analysis) are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than aggregated review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

*29 CFR 1960.70 requires each Federal agency to notify the Occupational Safety and Health Administration within 8 hours of a work-related incident which results in the death of an employee or the inpatient hospitalization of three or more employees.

APPENDIX D

PERFORMANCE IMPROVEMENT STANDARDS

PI.1 The leaders establish a planned, systematic, organization-wide approach to process design and performance measurement, analysis, and improvement.

PI.1.1 The activities are planned in a collaborative and interdisciplinary manner.

PI.2 New or modified processes are designed well.

PI.2.1 Performance expectations are established for new and modified processes.

PI.2.2 The performance of new and modified processes is measured.

PI.3 Data are collected to monitor the stability of existing processes, identify opportunities for improvement, identify changes that will lead to improvement, and sustain improvement.

PI.3.1 The organization collects data to monitor its performance.

PI.3.1.1 The organization collects data to monitor the performance of processes that involve risks or may result in sentinel events.

PI.3.1.2 The organization collects data to monitor performance of areas targeted for further study.

PI.3.1.3 The organization collects data to monitor improvements in performance.

PI.4 Data are systematically aggregated and analyzed on an ongoing basis.

PI.4.1 Appropriate statistical techniques are used to analyze and display data.

PI.4.2 The organization compares its performance over time and with other sources of information.

PI.4.3 Undesirable patterns or trends in performance and sentinel events are intensively analyzed.

PI.4.4 The organization identifies changes that will lead to improved performance and improve patient safety and reduce the risk of sentinel events.

PI.5 Improved performance is achieved and sustained.

APPENDIX E

INSTRUCTIONS FOR COMPLETING A WRAMC FORM 1811 RISK MANAGEMENT/QUALITY IMPROVEMENT REPORT

1. This form is available in all work areas. This form should be completed, filling out all appropriate fields, to include patient and unit identification, type of occurrence, professional descriptions of individuals involved, and patient outcomes. If the occurrence involves ward or clinic personnel, the form titled "Addendum to Risk Management/Quality Improvement Report" must be completed. If the incident is a fall, the "Evaluating Falls" addendum must be completed. If the event is a medication error, the "Evaluating Medication Errors" addendum must be completed.

The WRAMC 1811, and appropriate addendums should be completed by any individual in any department who identifies a potential (e.g., close call) or actual patient safety event. The original 1811 will be forwarded to the Performance Improvement Office with appropriate addendums within 24 hours of discovery of the event or on the first duty day following a weekend or holiday. One of the carbon copies will be forwarded to the staff member's unit, clinic, and or department manager as appropriate. The manager/supervisor will review the document, add any additional relevant information, and forward it to the WRAMC Performance Improvement Office within 72 hours of receipt. After review, the individual who initiated the report will receive acknowledgement of receipt of the report via email.

The Performance Improvement/Risk Management/Patient Safety Advisory Group reviews all 1811s on the next duty day after receipt, and requests subsequent information as appropriate. This review is described under the Appendix titled Patient Safety/Risk Management/Sentinel Event management.

Appendix F

INSTRUCTIONS FOR COMPLETING THE INPATIENT OCCURRENCE SCREEN CHECKLIST
(WRAMC Form 8-R)

All inpatient charts will have an Inpatient Occurrence Screen Checklist filled out by the attending provider. All positive screens will be reviewed by an appropriate staff reviewer or by the Chair of the Patient Care Assessment Committee for standard of care determination. The Chair of the Patient Care Assessment Committee will also review positive screens and will also make a determination regarding standard of care. Those felt to meet standard of care will be filed. Those which are not felt to meet standard of care by these reviewers, or those with issues regarding possibility of becoming PCEs will be forwarded to the Patient Care Assessment Committee for review and standard of care determination.

The proponent agency of this publication is the Director, Performance Improvement/Risk Management Office. Users are invited to send suggestions and comments on DA Form 2028 (Recommended changes to Publications and Blank Forms) to commander, Walter Reed Army Medical Center, Attn: MCHL-MAO-PI, Washington, DC 20307-5001.

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